REMARKS

Claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 are pending in the present application. Applicants have amended claims 1, 2, 4, 5-12, 18, 19, 21-28, 34-43, 49-52, 57-60, 65-68 and 73 by deleting the term "having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800" which was objected to by the Examiner. Applicants respectfully submit that the deletion of such term does not raise any issue of new matter and does place the present application in better condition for appeal. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 1-12. 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 will be under examination.

REJECTION OF CLAIMS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 stand rejected under 35 U.S.C. §112, second paragraph as failing to comply with the written description requirement. Specifically, the Office Action objected to the use of the terminology "having approximately 10% ethylene oxide by weight and having an average molecular weight of propylene oxide block of approximately 1800"

Applicants respectfully point out that the claims have been amended to delete such terminology objected to in the Office Action. Therefore, this ground of rejection is moot.

REJECTION OF CLAIMS UNDER 35 U.S.C. §103

Claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Curatolo et al., U.S. Patent No. 5,605,889 ("Curatolo") in combination with the International Patent WO 99/39731 ("the International Patent") for the reasons set forth in the Office Action of January 30, 2006.

Applicants respectfully disagree with this ground of rejection. The Office Action not only failed to establish a *prime facie* case of obviousness under the standard of M.P.E.P. § 2142,

but also failed to give due weight to the superior properties of the claimed methods. Specifically, Curatolo and the international patent do not provide any specific teaching, suggestion or motivation to a skilled artisan on how to obtain the claimed method of increasing the bioavailability of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol). Moreover, the International Patent does not provide any indication as to which drug on its list of hundreds of "biological agents" can achieve good delivery results when used with block co-polymers, let alone suggesting the use of a drug not on its list. In addition, Dr. Steve Sutton's declaration shows that the presence of poly(ethylene glycol)-block-poly(propylene glycol)-block-poly(ethylene glycol) increased the beagle dog's exposure to azithromycin by 121-240% as measured by jugular AUC_{0-24}. Such "superiority of a property shared with the prior art is evidence of nonobviousness," M.P.E.P. § 716.02 (a). Furthermore, Applicants enclose a copy of the claims from the issued Australian patent as an indication that the currently pending claims are patentable over the cited prior art references as the Australian claims are similar in scope to the currently pending claims in this case. Therefore, reconsideration and withdrawal of this ground of rejection are respectfully requested.

CONCLUSION

In view of the amendments and the remarks, early and favorable consideration of all pending claims are respectfully requested.

It is believed that no fee, other than the $450 two-month extension of time fee, is deemed necessary in connection with the filing of the present Amendment. However, if any other fees are required, the Commissioner is hereby authorized to charge any such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

Date: Oct. 18, 2006

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LETTERS PATENT

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STANDARD PATENT

STANDARD PATENT

I, Fatima Beattie, Commissioner of Patents, grant a Standard Patent with the following particulars:

Name and Address of Patentee:
Pfizer Products Inc., Eastern Point Road Groton Connecticut 06340 United States Of America

Names of Actual Inventors: William John Curatolo and George Hemenway Foulds

Title of Invention: Method of increasing the bioavailability and tissue penetration of azithromycin

Application Number: 23172/01

Term of Letters Patent: Twenty years from 22 February 2001

Priority Details:

Number	*Date*	*Filed with*
60/184273	23 February 2000	UNITED STATES OF AMERICA

COMMONWEALTH OF AUSTRALIA

Dated this 18 day of May 2006

F. BEATTIE

The claims defining the invention are as follow:

1. A method of increasing the bioavailability of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and pluronic L61.

2. The method as defined in claim 1, wherein said azithromycin and said pluronic L61 are each administered in an amount such that the combination is antimicrobially effective.

3. The method as defined in claim 1, wherein said bioavailability increase is measured in blood serum.

4. The method as defined in claim 1, wherein said pluronic L61 and azithromycin are co-administered separately.

5. The method as defined in claim 4, wherein said pluronic L61 and azithromycin are co-administered by different routes.

6. The method as defined in claim 5, wherein said pluronic L61 is administered orally and said azithromycin is administered intravenously.

7. The method as defined in claim 4, wherein said azithromycin and said pluronic L61 are both administered orally.

8. The method as defined in claim 1, wherein said pluronic L61 and azithromycin are co-administered together in a composition.

9. The method as defined in claim 1, wherein said pluronic L61 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 25%.

10. The method as defined in claim 9, wherein said pluronic L61 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 50%.

11. The method as defined in claim 10, wherein said pluronic L61 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 75%.

12. The method as defined in claim 1, wherein said increase is measured as an increase in AUC relative to dosing in the absence of pluronic L61.

13. A method of increasing the Cmax of azithromycin, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and pluronic L61.

14. The method as defined in claim 13, wherein said azithromycin and pluronic L61 are each administered in an amount such that the combination is antimicrobially

effective.

15. The method as defined in claim 13, wherein said Cmax increase is measured in blood serum.

16. The method as defined in claim 13, wherein said pluronic L61 and azithromycin are co-administered separately.

17. The method as defined in claim 16, wherein said pluronic L61 and azithromycin are co-administered by different routes.

18. The method as defined in claim 17, wherein said pluronic L61 is administered orally and said azithromycin is administered intravenously.

19. The method as defined in claim 16, wherein said azithromycin and said pluronic L61 are both administered orally.

20. The method as defined in claim 13, wherein said pluronic L61 and azithromycin are co-administered together in a composition.

21. The method as defined in claim 13, wherein said pluronic L61 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 25%.

22. The method as defined in claim 21, wherein said pluronic L61 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 50%.

23. A method as defined in claim 22, wherein said pluronic L61 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 75%.

24. A method of increasing the concentration of azithromycin in a cell or a tissue, comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and pluronic L61.

25. The method as defined in claim 24, wherein said azithromycin and said pluronic L61 are each administered in an amount such that the combination is antimicrobially effective.

26. The method as defined in claim 24, wherein said pluronic L61 and azithromycin are co-administered separately.

27. The method as defined in claim 26, wherein said pluronic L61 and azithromycin are co-administered by different routes.

28. The method as defined in claim 27, wherein said pluronic L61 is administered orally and said azithromycin is administered intravenously.

29. The method as defined in claim 24, wherein said azithromycin and said pluronic L61 are both administered orally.

30. The method as defined in claim 24, wherein said pluronic L61 and azithromycin are co-administered together in a composition.

31. The method as defined in claim 24, wherein said pluronic L61 is co-administered in an amount such that said concentration of azithromycin is increased by at least 25%.

32. The method as defined in claim 31, wherein said pluronic L61 is co-administered in an amount such that said concentration of azithromycin is increased by at least 50%.

33. The method as defined in claim 32, wherein said pluronic L61 is co-administered in an amount such that said concentration of azithromycin is increased by at least 75%.

34. A composition comprising azithromycin and pluronic L61, said pluronic L61 being present in an amount such that, following administration, the azithromycin has an oral bioavailability greater than 37%.

35. The composition as defined in claim 34, wherein said pluronic L61 is present in an amount such that said oral bioavailability of azithromycin is increased by at least 25%.

36. The composition as defined in claim 35, wherein said pluronic L61 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 50%.

37. The composition as defined in claim 36, wherein said pluronic L61 is co-administered in an amount such that the oral bioavailability of azithromycin is increased by at least 75%.

38. A composition which increases the Cmax of azithromycin, comprising azithromycin and pluronic L61.

39. The composition as defined in claim 38, wherein said pluronic L61 is present in an amount such that said Cmax is increased by at least 25%.

40. The composition as defined in claim 39, wherein said pluronic L61 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 50%.

41. The composition as defined in claim 40, wherein said pluronic L61 is co-administered in an amount such that the Cmax of azithromycin is increased by at least 75%.

42. A composition which increases the concentration of azithromycin in a cell or a tissue, comprising azithromycin and pluronic L61.

43. The composition as defined in claim 42, wherein said pluronic L61 is present in an amount such that said increase is at least 25%.

44. The composition as defined in claim 43, wherein said pluronic L61 is co-administered in an amount such that said increase is at least 50%.

45. The composition as defined in claim 44, wherein said pluronic L61 is co-

administered in an amount such that said increase is at least 75%.

46. A kit comprising:

(1) a therapeutically effective amount of a composition comprising azithromycin, plus a pharmaceutically acceptable carrier or diluent, in a first dosage form;

(2) a therapeutically effective amount of a composition comprising a compound which is pluronic L61 , plus a pharmaceutically acceptable carrier or diluent, in a second dosage form; and

(3) a container for containing said first and second dosage forms,

when used for increasing the bioavailability of azithromycin, increasing the C_{max} of azithromycin, or increasing the concentration of azithromycin in a cell or tissue of a mammal.

47. The kit when used according to claim 46, wherein said kit is adapted for administration to a human.

48. The kit when used according to claim 46, wherein said kit further comprises directions for the administration of said compositions.

49. A combination of azithromycin and pluronic F61 when used for increasing the bioavailability of azithromycin.

50. A combination of azithromycin and pluronic F61 when used for increasing the Cmax of azithromycin.

51. A combination of azithromycin and pluronic F61 when used for increasing the concentration of azithromycin in a cell or a tissue.

52. Use of a combination of azithromycin and pluronic F61 in the manufacture of a medicament for increasing the bioavailability of azithromycin.

53. Use of a combination of azithromycin and pluronic F61 in the manufacture of a medicament for increasing the Cmax of azithromycin.

54. Use of a combination of azithromycin and pluronic F61 in the manufacture of a medicament for increasing the concentration of azithromycin in a cell or a tissue.

Dated 5 December, 2005
Pfizer Products Inc.

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